REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated September 14, 2006 are respectfully requested.

Applicants petition the Commissioner for a three-month extension of time. A separate petition accompanies this amendment.

I. Amendments

Claim 1 is amended to recite the tissue contacting surface distal end is substantially planar having a plurality of apertures each positioned on the tissue contacting surface.

Claim 10 is amended to recite the housing has a substantially planar distal end and the at least one aperture is positioned in the tissue contacting surface.

Claim 20 is amended to recite a substantially planar tissue contact surface and that the plurality of electrodes is configured to be selectively advanced from the housing interior substantially normal to the plane of the tissue contacting surface.

Basis for these amendments can be found, for example, in Fig. 1.

Claim 7 is amended to correct an obvious typographical error.

No new matter is added by way of these amendments.

II. Rejection under 35 U.S.C § 102

Claims 1-20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Edwards *et al.* (U.S. Patent No. 5,370,675).

These rejections are respectfully traversed.

A. The Present Claims

The present invention, as embodied by amended claim 1, describes a method of controlling an ablation volume depth during surface treatment of a target tissue site. The method includes a step of providing a tissue surface treatment apparatus comprising a housing having a proximal end and a distal end including a substantially planar tissue contacting surface having a plurality of apertures each positioned on the tissue contacting surface, the housing defining an interior, an energy delivery device including a plurality of

electrodes, each with a tissue penetrating distal end, the plurality of electrodes configured to be advanced from the housing interior through an aperture of the plurality of apertures and into a target tissue site to define an ablation volume at least partly bounded by the tissue surface; an advancement device disposed inside the housing interior and being coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

Claim 10 relates to a method of surface treatment of a target tissue site comprising providing a tissue surface treatment apparatus; positioning the apparatus at the target tissue site; deploying the expandable member to at least partially engage the target tissue surface; advancing the plurality of electrodes to the selected deployment depth beneath a tissue surface while avoiding a critical structure; delivering ablative energy from the energy delivery device; creating an ablation volume at a controlled depth below the tissue surface responsive to the electrode deployment depth; and minimizing injury to the critical structure responsive to the electrode deployment depth.

The tissue surface treatment apparatus comprises a housing having a proximal end and a substantially planar distal end having at least one aperture positioned in the distal end, an expandable member positioned at the distal end of the housing and including a tissue contacting surface, the expandable member having a non-deployed state and an expanded or deployed state, and an energy delivery device, the energy delivery device including a plurality of electrodes each with a tissue penetrating distal end, the plurality of electrodes being selectively advanceable through the at least one aperture and by or through the expandable member to an individual selected deployment depth within the target tissue site to define an ablation volume at least partly bounded by the tissue surface.

Claim 20, as amended, is directed to a method of controlling an ablation volume depth during surface treatment of a target tissue site. The method comprises providing a tissue surface treatment apparatus; positioning the tissue contact surface on a target tissue surface; at least partially immobilizing the tissue surface utilizing the tissue contact surface; selectively advancing the plurality of electrodes to the selected deployment depth

beneath a tissue surface while avoiding a critical structure; delivering ablative energy from the energy delivery device; creating an ablation volume at a controlled depth below the tissue surface responsive to the electrode deployment depth; and minimizing injury to the critical structure responsive to the electrode deployment depth. The apparatus comprises a housing having a proximal end and a distal end having a substantially planar tissue contact surface configured to at least partially immobilize the tissue surface, the housing defining an interior; an energy delivery device positionable in the housing interior, the energy delivery device including a plurality of electrodes with a tissue penetrating distal end, the plurality of electrodes configured to be selectively advanced from the housing interior substantially normal to the plane of the tissue contacting surface to an individual selected deployment depth in a target tissue site to define an ablation volume at least partly bounded by the tissue surface; an advancement device disposed inside the housing interior and being coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth;

B. The Cited Art

EDWARDS ET AL. describe a medical probe device for treatment of the hyperplastic tissues of the prostate to treat benign prostatic hyperplasia. The probe comprises a catheter and a stylet guide housing positioned at the distal end of the catheter for directing one or more flexible stylets out of the catheter and into the tissue.

C. Analysis

1. Claim 1

The method of instant claim 1 includes providing an apparatus including a housing having a proximal end and a distal end including a substantially planar tissue contacting surface and having a plurality of apertures each positioned on the tissue contacting surface.

Edwards *et al.* fail to teach a step of providing such an apparatus. As seen in Fig. 2, the apparatus as described by Edwards *et al.* includes a stylet guide 16 that is

positioned between annular balloons 30 and 32. The stylet guide does not have a substantially planar tissue contacting surface having a plurality of apertures. Instead, stylets 36 are deployed radially from the stylet guide to the side of the catheter. The apertures of the Edwards *et al.* device are positioned circumferentially around the stylet guide and not in a substantially planar tissue contacting surface at the distal end of the housing.

The Examiner further points to Fig. 14 for a teaching of the step of providing an apparatus as presently claimed. However, this figure shows a "four-probe embodiment of the device" (Col. 14, lines 12-13) with a handle portion 180 and a catheter portion 182. As seen in the figure, the stylets are also deployed radially from the side of the catheter probe.

Nor could the stylets deploy from a substantially planar tissue contacting surface as the device is especially designed to deploy a flexible catheter through the urethra to a position adjacent the prostate. The stylets are deployed into the urethral wall and into the prostate. An object of the Edwards *et al.* patent is to precisely target tissue and to minimize the trauma to the urethra (Col. 3, lines 17-23). Were the stylets to deploy from a plane, they would need to be stacked as the stylet guide is cylindrical. This would make multiple punctures in the urethra and may not effectively target the prostate.

2. Claim 10

Claim 10 describes a similar method including providing a tissue surface treatment apparatus including a housing having a substantially distal end and a plurality of electrodes configured to be selectively advanced from the housing interior substantially normal to the plane of the tissue contacting surface. This claim, and the claims dependent thereon, patentably define over the prior art substantially for the same reasons discussed above. Briefly, Edwards *et al.* teach stylets that are deployed radially from the stylet guide to the side of the catheter. The apertures of the Edwards *et al.* device are positioned circumferentially around the stylet guide and not in a substantially planar tissue contacting surface at the distal end of the housing.

Nor could the stylets deploy from a substantially planar tissue contacting surface as the device is especially designed to deploy a flexible catheter through the urethra to a position adjacent the prostate. The stylets are deployed into the urethral wall and into the prostate. An object of the Edwards *et al.* patent is to precisely target tissue and to minimize the trauma to the urethra (Col. 3, lines 17-23). Were the stylets to deploy from a plane, they would need to be stacked as the stylet guide is cylindrical. This would make multiple punctures in the urethra and may not effectively target the prostate.

3. Claim 20

Claim 20, as amended, recites providing a tissue surface treatment apparatus including a housing having a distal end having a substantially planar tissue contacting surface and a plurality of electrodes configured to be selectively advanced from the housing interior substantially normal to the plane of the tissue contacting surface. As noted above with reference to claim 1, the apparatus as described by Edwards *et al.* includes a stylet guide 16 that is positioned between annular balloons 30 and 32. The stylet guide does not have a substantially planar tissue contacting surface having a plurality of apertures. Instead, stylets 36 are deployed radially from the stylet guide to the side of the catheter. The apertures of the Edwards *et al.* device are positioned circumferentially around the stylet guide and not in a substantially planar tissue contacting surface at the distal end of the housing.

Nor could the stylets deploy from a substantially planar tissue contacting surface as the device is especially designed to deploy a flexible catheter through the urethra to a position adjacent the prostate. The stylets are deployed into the urethral wall and into the prostate. An object of the Edwards *et al.* patent is to precisely target tissue and to minimize the trauma to the urethra (Col. 3, lines 17-23). Were the stylets to deploy from a plane, they would need to be stacked as the stylet guide is cylindrical. This would make multiple punctures in the urethra and may not effectively target the prostate.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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